K002731

NOV 2 0 2000

510(k) Premarket Notification
N Latex ß$_2$-Microglobulin
August 31, 2000

Dade Behring Inc.
7739 NW 48th Street
Miami, FL 33166
Contact Person: Radames Riesgo at 305.392.5639 or by facsimile at 305.392.5638.

Trade or Proprietary Name: N Latex ß$_2$-Microglobulin

Common or Usual Name: Reagents for the quantitative determination of ß$_2$-microglobulin

Classification Name: Beta-2-microglobulin immunological test system
(21 CFR § 866.5630)

Registration Number:

Manufacturing Site
Dade Behring Marburg GmbH
Emil-von-Behring Str. 76
Marburg, Germany 9610806

Distributor
Dade Behring Inc.
Glasgow Site
P.O. Box 6101
Newark, DE 19714-6101 2517506

The N Latex ß$_2$-Microglobulin is an *in vitro* diagnostic reagent intended to be used with the Behring Nephelometer Systems in the quantitative determination of ß$_2$-microglobulin in serum, plasma or urine.

In the proposed device, polystyrene particles coated with specific antibodies to human ß$_2$-microglobulin are agglutinated when mixed with samples containing ß$_2$-microglobulin. The intensity of the resulting scattered light measured by the nephelometer is dependent upon the ß$_2$-microglobulin content in the sample and consequently its concentration can be determined by comparison with dilutions of a standard of known concentrations.

N Latex ß$_2$-Microglobulin, is substantially equivalent in intended use and results to the IMx ß$_2$-Microglobulin device, Abbott Laboratories, Diagnostics Division, Abbott Park, IL 60064. The Abbott IMx ß$_2$-Microglobulin reagent was cleared by FDA under Document Control No. K890421.

In a comparative study between the N Latex β_2-Microglobulin and the Abbott IMx β_2-Microglobulin involving 120 serum specimens the coefficient of correlation obtained was 0.993 and the regression equation was $Y = 1.06X + 0.02$. In a comparative study using 106 urine specimens the coefficient of correlation obtained was 0.986 and the regression equation was $Y = 1.03X - 0.04$.

Precision studies were performed by the evaluation of two different concentrations of control materials and three different concentrations each of pooled serum and of pooled plasma. The results yielded a total coefficient of variation of 2.2 to 3.6%, a between-run coefficient of variation of 1.0 to 2.5%, and a within-run coefficient of variation of 1.7 to 3.0%.

The precision studies for the urine assay were conducted using two different concentration of control material and three different concentrations each of pooled urine. The results yielded a total coefficient of variation of 4.5 to 5.3%, a between-run coefficient of variation of 3.7 to 4.5%, and a within-run coefficient of variation of 2.7 to 3.1%.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 2 0 2000

Mr. Radames Riesgo
Manager, Regulatory Affairs and Compliance
DADE BEHRING, INC.
7739 NW 48th Street, Suite 120
Miami, Florida 33166

Re: K002731
Trade Name: N Latex β_2-Microglobulin
Regulatory Class: II
Product Code: JZG
Dated: November 3, 2000
Received: November 6, 2000

Dear Mr. Riesgo:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K002731

Device Name: N Latex β_2-Microglobulin

Indications for Use:

N Latex β_2-Microglobulin is an in vitro diagnostic reagent for the quantitative determination of human β_2-microglobulin in serum, plasma (EDTA and heparinized), as well as urine by means of particle-enhanced immunonephelometry on the BN systems. The assay of β_2-microglobulin is helpful in the diagnosis of active rheumatoid arthritis and renal diseases.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Peter F. Maker

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K002731

Prescription Use ✓ OR Over-The-Counter-Use _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)